APPENDIX C - Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.

Introduction

Chapter 6 of the NELAC standards defines the process and criteria used by NELAP to determine whether an accrediting authority meets the standards required for recognition. Under this standard (Section 6.2.3.a.1), accrediting authorities are required to maintain documentation about the laboratory accreditation process. Section 6.3.3.1.3.b.8 also states that the accrediting authority's Quality Manual shall include the policies and procedures to implement the accreditation process.

This appendix summarizes the elements to be included by accrediting authorities in SOPs describing on-site assessments of laboratories seeking accreditation under the NELAC standards. At a minimum, the following elements shall be included in the SOPs to ensure consistency of laboratory assessments performed by accrediting authorities.

Pre-Assessment

1. Assessment Planning: The SOP describes how the type of assessment is determined, e.g., initial, renewal, follow-up, etc. Also includes procedures for determining whether the assessment is announced or unannounced, the scope of accreditation (technology, matrix, method, analyte or analyte groups), the estimated time spent on-site, and the assessment team resources needed. The SOP will also address preparation of the on-site assessment agenda.

2. Assessment Team: The SOP describes the qualifications, roles, and responsibilities of the assessment team members, e.g., lead assessor, assessors, and technical support personnel. The SOP shall also include assessment team procedures followed if improper or potentially illegal activities are encountered. The SOP shall detail the circumstances under which the assessment may be terminated including how the assessment team communicates this to the accrediting authority.

3. Document Review:

a. The SOP shall describe how the assessment team will identify and select specific documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.12. The SOP shall specify that the document review process includes the following records: the laboratory's accreditation application, previous assessment and PT reports, laboratory organization charts, qualifications statements for all staff involved in the analysis or reporting of results, the laboratory QA manual, SOPs for the fields of testing for which accreditation is sought, laboratory instrumentation and equipment records, standard and reagent preparation documentation, initial method validation studies, Demonstration of Capability test method precision and accuracy records, sample receipt and handling, internal audit records, and the laboratory's annual management review. Other documents required for review should be described in the SOP: Document control records, corrective action records, complaints records, subcontracting registry, uncertainty calculations (currently needed for WET and Radiochemistry), and an example client report.

b. Findings or observations made during the preliminary document review will be used to determine if the laboratory is ready for an on-site assessment. The accrediting authority may present preliminary findings before the on-site assessment so the laboratory has time to correct them before the assessment team arrival. If the assessment team determines that the laboratory is not ready for an on-site assessment, the SOP shall describe the procedures for laboratory notification.

4. Accrediting Authority Standardized Assessment Documents and Forms: The SOP describes the documents required for the assessment, and which should be assembled prior to the assessment, e.g., Confidentiality Notice, Conflict of Interest Form, Assessor Credentials, Assessment Notification Letter, Attendance Sheets for opening and closing conferences, standardized NELAC checklists, and Assessment Appraisal Forms.

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5. Confidential Business Information: The SOP explains the procedures for handling confidential business information in compliance with federal regulations (40 CFR Part 2) and applicable state regulations.
6. National Security Considerations: The SOP describes procedures for handling security requirements at Federally owned or operated facilities.

Assessment

1. Opening Conference: The SOP describes procedures for the opening conference and details the topics to be covered, including the scope of the assessment, the schedule with a tentative time for the exit conference, the NELAC standards used for the assessment, identification of the assessment team, test methods to be examined, records and SOPs required, Confidential Business Information, roles and responsibilities of the laboratory staff, the Assessment Appraisal Form, laboratory questions about the assessment process, and laboratory safety procedures to be followed by the assessment team (lab coats, safety glasses, etc.).
2. Records Review and Collection: In general the assessment team must determine the extent of traceability of standards, personnel training, documents, samples, data, records and problems/resolution (corrective action/follow-up). The SOP describes the procedures to be followed for records review by the assessment team during the on-site visit and the criteria the assessment team will use to determine the accuracy and completeness of the records reviewed or collected during the assessment, e.g., data review includes tracing samples from receipt to verification of final results, training records review includes a representative sampling from all operational and support areas, etc.
3. Assessment Areas: The SOP describes the areas to be evaluated against NELAC Chapter 5 standards during the assessment, e.g., the laboratory facility, laboratory organization and management, qualifications of laboratory staff, sample handling including receipt and tracking, instrumentation, standards traceability, test methods, data reduction and reporting procedures, and quality control procedures. Additionally, the SOP defines what is objective evidence of conformance to the standard, e.g., records or words or just assessor observation. The SOP also describes the procedures to determine the compliance tools to be used in evaluation of these areas
4. Staff Interviews: The SOP describes the procedures for conducting staff interviews.
5. Closing Conference: The SOP details the procedures to be followed for the closing conference, including the presentation process of deficiencies at the closing conference (written, checklist, verbal), discussion of deficiencies, notification that the assessment team may identify additional deficiencies in the final report, handling disputed findings, when to expect the assessment report, and schedule for renewal and reassessment.

Assessment Reporting

1. Assessment Report: The SOP describes the requirements for the final site report, including the format. The assessment report shall contain the name and address of the audited organization, the date of the assessment, identification and affiliation of the each assessment team member, identification of participants in the assessment, a statement of the objective of the assessment, summary, identification of deficiencies with reference to the specific NELAC standard(s), and comments and recommendations.
2. Roles and Responsibilities: The SOP addresses the roles and responsibilities of the accrediting authority and the assessment team in the report generations, distribution, and release procedures.
3. Report Release: The SOP describes the requirements for release of the assessment report to the laboratory and to the public. The SOP shall address exemptions to the release of proprietary information.

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Assessment Closure

1. Evaluation of the Laboratory's Corrective Action Plan: The SOP describes the accrediting authority's procedures for evaluating the laboratory's corrective action plan.

2. Roles and Responsibilities: The SOP details the roles and responsibilities of the assessment team and the accrediting authority in the evaluation of the laboratory's corrective action report in response to the on-site assessment and in the determination of accreditation status.

3. Follow-up Assessments: The SOP describes the circumstances under which a follow-up assessment would be necessary. The SOP also addresses the minimum documentation required for a follow-up assessment.

4. Record Retention: The SOP defines the record retention policy for documentation used in or obtained during an assessment, including assessment reports, checklists, and laboratory responses.